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09/987,899	11/16/2001	Nordine Cheikh	16517.258	7754

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EXAMINER	
MARSCHEL, ARDIN H	
ART UNIT	PAPER NUMBER
1631	10

DATE MAILED: 12/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/987,899	Applicant(s) CHEIKH ET AL.	
	Examiner Ardin Marschel	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 10-22* is/are pending in the application.

4a) Of the above claim(s) *10-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 2* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,2 and 10-22* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892) (2 sheets)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) (11 sheets)
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant's election with traverse of Group I (claims 1, 2, and 10-21) and SEQ ID NO: 5 in Paper No. 9, filed 4/15/03, is acknowledged. It is noted, however, that claims 10-21 cite and therefore are directed to sequences other than SEQ ID NO: 5 and thus are non-elected due to the sequence election of SEQ ID NO: 5. Therefore, only instant claims 1 and 2 are presently under examination.

The traversal is on the ground(s) that the complete examination would be handled most expeditiously by treating all of the pending claims as a single entity. This is not found persuasive because the undue search burden involved with examination of all of the pending claims together has been set forth in the previous office action, mailed 3/5/03, and the above allegations of applicants has not addressed nor negated the previously set forth undue search burden of examining all of the pending claims as a single entity. It is also noted that the above argument lacks specificity as to whether it was directed to also including the examination of sequences other than SEQ ID NO: 5 or not. In case that this was also meant, it is reiterated from the previous office action, mailed 3/5/03, that other sequences are unrelated as apparently being directed to structurally distinct genes and/or mRNA sequences as chemical compounds. Applicants argue further that a method of determining an association between a polymorphism and a plant trait utilizes SEQ ID NO: 5 as a nucleic acid. This is acknowledged, however, the distinctness between said method and the nucleic acids of Group I was previously set forth in the previous office action, mailed 3/5/03, due to a number of materially different processes of use and not only that one is claimed.

Applicants have not addressed the presence of such materially different processes of use for the Group I invention and therefore have set forth arguments which are not directed to the basis for the restriction requirement and therefore are non-persuasive. Applicants lastly argue that SEQ ID NO: 5 is not patentably distinct from the other sequences listed in claim 2, for example. This argument has been answered above and is reiterated here as being equally non-persuasive.

The requirement is still deemed proper and is therefore made FINAL.

LACK OF UTILITY REJECTION

The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. § 112, first paragraph, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is specific to the subject matter claimed. This contrasts with a general utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

35 U.S.C. § 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 1 and 2 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

The claimed subject matter is not supported by a specific, substantial, and credible utility because the disclosed uses are generally applicable to broad classes of this subject matter. In addition, further characterization of the claimed subject matter would be required to identify or reasonably confirm a "real world" use. The examiner does not find an adequate nexus between the evidence of record and the asserted properties of the claimed subject matter.

It is noted that the specification describes a plethora of enzymes with their corresponding activities but lacks any specific or substantial connection disclosure between the elected SEQ ID NO: 5 and any of the described enzymes. It is additionally noted that a sequence similarity score is cited in Table A on page 254 of the specification to a library with a clone ID. Such a similarity scoring method also lacks substantial utility description as also more fully described in the following paragraph.

It is noted that applicant has identified a sequence which has a stated sequence similarity to the claimed sequence as in Table A on page 254 regarding SEQ ID NO: 5. Absent factual evidence, one skilled in the art would have reason to doubt that sequence similarity alone would reasonably support the assertion that the biological activity of the claimed subject matter would be the same as that of the similar sequence. Furthermore, it is unclear whether the similar sequence has actually been tested for the biological activity or whether this also is an asserted biological activity based upon sequence similarity to yet a different sequence. Note that it would have been well known in the art that sequence similarity does not reliably correlate to structural similarity and that structural similarity does not reliably result in similar or identical biological activities. For example, it would have been well known that even a single nucleotide or amino acid change or mutation can destroy the function of the biomolecule in many instances, albeit not in all cases. In the absence of factual evidence characterizing the structural and functional components of the biomolecule, the effects of these changes are largely unpredictable as to which ones will have a significant effect and which ones will be silent mutations having no effect. Several publications document the unpredictability of the relationship between sequence, structure, and function, although it is acknowledged that certain specific sequences have been found to be conserved in biomolecules having related function following a significant amount of further research. See Attwood (Science, 290:471-473, 2000); Gerhold et al. (BioEssays, 18(12):973-981, 1996); Wells et al. (Journal of Leukocyte Biology, 61(5):545-550, 1997); Russell et al. (Journal of Molecular Biology, 244:332-350, 1994);

and Lopez et al. (Molecular Microbiology, 32: 881-891, 1999). However, this level of factual evidence is absent here.

Applicant should explicitly identify a specific, substantial, and credible utility for the claimed invention and establish a probative relation between any evidence of record and the originally disclosed properties of the claimed invention.

LACK OF ENABLEMENT REJECTION

Claims 1 and 2 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by a specific, substantial, and credible utility or a well-established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

VAGUENESS AND INDEFINITENESS

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 2, cites the phrase "or fragment thereof". This causes the claim to be vague and indefinite as to what is meant thereby. A fragment without definition as to its metes and bounds could be as small as a single nucleotide or a short polymer fragment etc. As worded the claim is also unclear whether the fragment is required to encode an enzyme of a carbon assimulation pathway or not. It is noted that the specification discusses fragment nucleic acid molecules in the specification on page 70, lines 3-6, but does not set forth any metes and bounds for what is meant thereby. Clarification via clearer claim wording is requested.

LACK OF WRITTEN DESCRIPTION

Claims 1 and 2 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses SEQ ID NO: 5 which corresponds to the cDNA/genomic DNA presumably encoding an enzyme. SEQ ID NO: 5 per se meets the written description and enablement provisions of 35 USC 112, first paragraph. However, claims 1 and 2 are directed to encompass gene sequences, allelic variants within SEQ ID NO: 5 via the fragments of claim 1 as well as flanking variants included withint claim 2. None of these additional sequences meet the written description provision of 35 USC § 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO: 5, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmacentical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.

Therefore, only SEQ ID NO: 5 but not the full breadth of the claims meet the written description provision of 35 USC § 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See page 1115.)

PRIOR ART

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by the 1990 Sigma Chemical Catalog disclosure of either of products O 4128, O 8628, or O 8878.

Product O 4128 is the fragment dinucleotide $d(pA)_2$ which anticipates the fragment of instant SEQ ID NO: 5 at bases 11-12 which is also A-A. Several other A-A

fragments are present as shown in instant SEQ ID NO: 5. The fragment C-C-C is present within instant SEQ ID NO: 5 at positions 144-146 which is anticipated by the trinucleotide of product O 8628 of said Sigma Chemical Catalog. Similarly, the pentanucleotide C-C-C-C-C fragment of instant SEQ ID NO: 5 at positions 285-289 is anticipated by the oligodeoxycytidylic acid which is a cytidylic pentanucleotide of product O 8878.

CLAIMS OBJECTIONS

Claims 1 and 2 are objected to due to being inclusive of subject matter directed to sequences other than the elected SEQ ID NO: 5.

INFORMALITIES

The disclosure is objected to because of the following informalities:

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See, for example, page 18, last 4 lines, and page 19, first 4 lines, of the specification. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Appropriate correction is required.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is

(703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

November 28, 2003

ARDIN H. MARSCHEL
PRIMARY EXAMINER